OCT 2 4 2002

K023182

Índigo® OPTIMA Laser System
510(k) Summary of Safety & Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Carol Sprinkle
Regulatory Affairs Specialist

Date Prepared
September 23, 2002

Name of Device
Trade Name: Índigo® OPTIMA Laser System
Classification Name: Laser powered surgical instrument

Predicate Device
Índigo® OPTIMA Laser System (K013493)

Device Description
The Índigo® OPTIMA Laser System consists of a treatment diode laser, fiberoptic energy delivery devices, a footswitch, and an optional cart with printer. The treatment laser allows delivery of controlled doses of laser energy in wavelengths between 800 and 850 nanometers (nm). When used with the OPTIMA Diffuser-Tip Fiberoptic, this laser energy is diffused radially at 360° to the affected tissue to provide interstitial thermotherapy (ITT), or interstitial laser coagulation (ILC). The fiberoptics (fibers) are designed to be sterile, single patient use, disposable devices.

Modifications to design of the Diffuser-Tip Fiberoptic have been made to improve manufacturability. Changes include removal of the inner sleeve, use of a new non patient-contacting adhesive, and a software modification.

Intended Use
The Índigo OPTIMA Laser System when used with the Diffuser-Tip Fiberoptic is intended for the safe and effective treatment of symptoms of benign prostatic hyperplasia (BPH).

Comparison of Technological Characteristics
The technological features of the modified Diffuser-Tip Fiberoptic are the same as the predicate with exception of the above design changes. The operating parameters of the laser have been adjusted slightly to accommodate the design changes with no loss in performance. No new issues of safety and effectiveness have been raised by these modifications.

Performance Data
Design verification and validation testing confirms the modified Diffuser-Tip Fiberoptic performs as intended and is equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Ms. Carol Sprinkle
Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K023182
Trade/Device Name: Indigo® OPTIMA Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 23, 2002
Received: September 24, 2002

Dear Ms. Sprinkle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023182

Device Name: **Índigo® OPTIMA Laser System**

Indications for Use:

The Índigo OPTIMA Laser System with Diffuser-Tip Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85 cc; and for general surgery, general urological, general gynecological and general gastroenterological procedures; and coagulative necrosis and interstitial laser coagulation of soft tissues such as tumors and fibroids.

The Índigo OPTIMA Laser System, when used in conjunction with the Bare-Tip Fiberoptic, is indicated for the incision, excision, and ablation or coagulation of tissues with hemostasis during general surgery, and general gastroenterological and urological procedures, including those involving urethral strictures, bladder neck contractures, and condylomata.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023182

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription use ✓